

## CLAIMS

1. A process for the production of sertraline salt comprising the steps of :
  - a) dissolving or suspending sertraline mandelate in a solvent ;
  - 5 b) reducing the pH of the solution or the suspension, and
  - c) isolating salt of sertraline.
2. A process for the production of sertraline hydrochloride Form - V comprising the steps of :
  - 10 a) dissolving or suspending sertraline mandelate in a solvent ;
  - b) reducing the pH of the solution or the suspension, and
  - c) isolating sertraline hydrochloride Form V.
3. The process as claimed in claim 1 or 2, wherein solvent used in step (a) is a protic  
15 solvent or a mixture of protic solvents selected from the group comprising of  
protic solvents or mixtures thereof.
4. The process as claimed in claim 3, wherein protic solvent(s) used in step (a) is  
selected from the group comprising of alcohol, water or mixtures thereof.
- 20 5. The process as claimed in claim 4, wherein said alcoholic solvent used in step (a)  
is selected from the group comprising of methanol, ethanol, n-propyl alcohol,  
isopropyl alcohol, n-butyl alcohol, t-butyl alcohol, isobutyl alcohol or mixtures  
thereof.

6. The process as claimed in claim 5, wherein said alcoholic solvent is isopropyl alcohol.
7. The process as claimed in claim 1 or 2 wherein said step(a) of dissolving or  
5 suspending is achieved by heating and / or stirring.
8. The process as claimed in claim 1 or 2, wherein said step (a) of dissolving or  
suspending sertraline mandelate in a solvent is carried out at temperature in the  
range of 20 to 90 °C.
- 10 9. The process as claimed in claim 8, wherein said range of temperature is 25 to  
80°C.
10. The process as claimed in claim 9, wherein said range of temperature is 25 to  
15 30°C.
11. The process as claimed in claim 1 or 2, wherein an organic or inorganic acid is  
used for reduction of pH in step (b).
- 20 12. The process as claimed in Claim 11, wherein said acid used for reduction of pH is  
an inorganic acid.
13. The process as claimed in claim 12 wherein said acid is HCL.

14. The process as claimed in claim 13, wherein HCl is used in the form of a gas or dissolved in solvent.
15. The process as claimed in 14, wherein said solvent is water or organic solvent or mixtures thereof.
16. The process as claimed in claim 15, wherein said organic solvent is alcohol.
17. The process as claimed in claim 16, wherein said alcohol is selected from the group comprising of methanol, ethanol, n-propanol, isopropyl alcohol, n-butanol or mixtures thereof.
18. The process as claimed in claim 1 or 2, wherein pH is reduced to the range of 1 to 3 in step (b).
19. The process as claimed in claim 18, wherein pH is reduced to the range of 1 to 2.
20. The process as claimed in claim 2, wherein isolation of sertraline hydrochloride Form V in step (c) is carried out by cooling the contents of step (b).
21. The process as claimed in claim 20, wherein the cooling is effected by allowing the solution to attain room temperature on its own or with mild coolants comprising of cold water, water, alcohol or mixtures thereof.

22. The process as claimed in claim 21, wherein said alcohol is selected from the group comprising of monohydroxy alcohols, dihydroxy alcohols or mixtures thereof.

5 23. Sertraline hydrochloride Form - V characterized by a powder X-ray diffraction pattern with peaks at about (2 Theta Values) :  $5.2 \pm 0.2$ ,  $10.9 \pm 0.2$ ,  $14.1 \pm 0.2$ ,  $16.3 \pm 0.2$ ,  $17.1 \pm 0.2$ ,  $19.0 \pm 0.2$ ,  $19.7 \pm 0.2$ ,  $20.9 \pm 0.2$ ,  $22.0 \pm 0.2$ ,  $23.0 \pm 0.2$ ,  $23.5 \pm 0.2$ ,  $25.3 \pm 0.2$ ,  $25.9 \pm 0.2$  and  $29.0 \pm 0.2$  degrees two-theta and an IR spectrum with peaks at about  $773 \text{ cm}^{-1}$ ,  $1011 \text{ cm}^{-1}$ ,  $1032 \text{ cm}^{-1}$ ,  $1054 \text{ cm}^{-1}$ ,  $1134$   
10  $\text{cm}^{-1}$ ,  $1330 \text{ cm}^{-1}$ ,  $1561 \text{ cm}^{-1}$  and  $1591 \text{ cm}^{-1}$ .

24. Sertraline hydrochloride Form - V characterized by powder X-ray diffraction (XRPD) pattern substantially as set out in the Table given below:

| Serial No. | Diffraction Angle $\pm 0.2^\circ$<br>(degree two theta) | Lattice Spacing (D)<br>(Angstroms) |
|------------|---|------------------------------------|
| 1          | 5.2   | 17.119                             |
| 2          | 10.9  | 8.122                              |
| 3          | 14.1  | 6.259                              |
| 4          | 16.3  | 5.433                              |
| 5          | 17.1  | 5.181                              |
| 6          | 19.0  | 4.671                              |
| 7          | 19.7  | 4.506                              |
| 8          | 20.9  | 4.256                              |
| 9          | 22.0  | 4.046                              |

| Serial No. | Diffraction Angle $\pm 0.2^\circ$<br>(degree two theta) | Lattice Spacing (D)<br>(Angstroms) |
|------------|---|------------------------------------|
| 10         | 23.0  | 3.860                              |
| 11         | 23.5  | 3.776                              |
| 12         | 25.3  | 3.517                              |
| 13         | 25.9  | 3.437                              |
| 14         | 29.0  | 3.075                              |

25. Sertraline hydrochloride Form V characterized by IR spectrum with peaks at about  $773\text{ cm}^{-1}$ ,  $1011\text{ cm}^{-1}$ ,  $1032\text{ cm}^{-1}$ ,  $1054\text{ cm}^{-1}$ ,  $1134\text{ cm}^{-1}$ ,  $1330\text{ cm}^{-1}$ ,  $1561\text{ cm}^{-1}$  and  $1591\text{ cm}^{-1}$ .

5

26. Sertraline hydrochloride Form - V as claimed in claim 25 further characterized by a powder X-ray diffraction pattern as substantially depicted in Fig 1 of the accompanying drawings.

10 27. Sertraline hydrochloride Form - V of Claim 25 or 26 further characterized by an IR spectrum as substantially depicted in Fig 2 of the accompanying drawings.

28. A process for preparation of a pharmaceutical composition of sertraline hydrochloride Form - V, comprising mixing sertraline hydrochloride Form-V, of  
15 particle size below  $20\mu$  is not less than 90 % with pharmaceutically acceptable diluent, carrier or excepiant.

29. The process for preparation of a pharmaceutical composition as claimed in claim 28, wherein the impurity level in sertraline hydrochloride Form V used is not more than 0.50% comprising of both known and unknown impurities.
- 5 30. The process for preparation of a pharmaceutical composition as claimed in claim 29, wherein the sulphated ash in sertraline hydrochloride Form V is not more than 0.2%.
- 10 31. The process for preparation of a pharmaceutical composition as claimed in claim 29, wherein the heavy metals in sertraline hydrochloride Form V used is not more than 20 ppm.
- 15 32. The process for preparation of a pharmaceutical composition as claimed in claim 28, wherein the assay by titration of sertraline hydrochloride Form V is between 98.0 to 102.0 % on anhydrous basis.
33. The process for preparation of a pharmaceutical composition of as claimed in claim 28, wherein the residual solvents in the active ingredient sertraline hydrochloride Form V are :
- |    |                        |   |                        |
|----|------------------------|---|------------------------|
| 20 | (e) isopropyl alcohol  | : | not more than 2000 ppm |
|    | (f) methanol           | : | not more than 100 ppm  |
|    | (g) acetone            | : | not more than 100 ppm  |
|    | (h) methylene chloride | : | not more than 200 ppm  |

34. The process for preparation of a pharmaceutical composition as claimed in claim 28, wherein the microbial limits in active ingredient sertraline hydrochloride Form V are :

5       total aerobic count (cfu/g)       :       not more than 1000  
      total fungal count (cfu/g)       :       not more than 100  
      E.Coli                               :       should be absent.

35. A process for the preparation of sertraline hydrochloride Form - V,  
10       substantially as herein described, particularly with reference to the foregoing  
      examples.